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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,452	10/23/1998	RHONA HARRIET BORTS	263/PPIR1165	8673

7590

04/25/2005

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,452

Applicant(s)

BORTS ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50,52,53,55 and 57-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50,52,53,55 and 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application is a 371 National stage filing of PCT/GB97/00875, filed March 27, 1997, which claims benefit to provisional application 60/014,490, filed April 1, 1996.

Applicants amendment filed March 8, 2004, has been received and entered. Claims 51, 54, 56 and 61-63 have been canceled. Claim 50 has been amended. Claims 50, 52, 53, 55, and 57-60 are pending.

Election/Restriction

As noted previously, the claims were amended from methods and processes practiced in the elected species of “animals” to methods encompassing the non-elected species of “yeast”.

Again, Applicant was required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon the allowance of a generic claim, applicant would be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In this case, Applicants have cancelled all the claims to the elected species, so a generic claim exists no longer exists. Claims 50, 52, 53, 55, and 57-60 are currently under examination as they are directed to the elected species of yeast.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50, 52, 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 50 has been amended in step (d) to require that meiotic recombination is affected to make a hybrid yeast, however the method also requires "maintaining the diploid yeast cells". Meiosis which results in a haploid cell and maintaining a diploid cell are inconsistent with each other. Furthermore, it is noted that the final step results only in a hybrid cell without any requirements that it has undergone meiosis or is a haploid cell.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50, 52, 53, 55, and 57-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case, the claims have been amended to recite that the method is practiced to effect "meiotic recombination", however the specification only provides support for "maintaining the mixture under conditions to effect meiosis" (page 3, lines 25-29) which is

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not sufficient to support "effect meiotic recombination" as recited in the amended claims.

Allowing for meiosis is not the same as providing the conditions in which recombination occurs.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 50, 52, 53, 55, and 57-60 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. Further, as taught by Selva et al. (1995), yeast comprising mutation(s) in their mismatch repair system affect recombination in mitotic cells. The instant specification teaches the same genes are responsible for mismatch repair, but fail to teach how they can be used to specifically affect meiotic recombination as required by the claims.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to

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determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50, 52, 53, 55, 57-60 stand rejected under 35 U.S.C. 102(b) as being anticipated by Selva *et al.* (IDS reference, March 1995).

Applicants not the amendments to the claims, and argue that Selva *et al.* fails to teach meiosis or that the disclosed methods can be used to effect meiotic recombination. Applicants' arguments have been fully considered, but not found persuasive.

The claims as amended requires providing conditions "to effect meiotic recombination to make a hybrid cell" however does not specifically require a method step that meiosis must or has occurred. Further, it is noted that the specific alterations that are required that result in the affect is not meiosis itself, rather an alteration in the mismatch repair system of genes such as PMS1 or MSH2 (claim 52 for example). Since Selva *et al.* teach yeast with the same genetic alterations as required by the claims and provide conditions for maintaining diploid cells, the methods of Selva *et al.* would anticipate the claims because they would inherently result in conditions that affect meiotic recombination, if meiosis were allowed to occur. Again, the claimed method comprises modifying genes encoding mismatch repair enzymes in yeast and allowing for homologous

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recombination of sequences that comprise up to 30% base mismatches. The dependent claims set forth specific mismatch repair enzymes and that the altered sequences are comprised in a gene which can be subsequently expressed. Selva *et al.* teach that altering mutL and mutS result in an increase in homologous recombination of divergent sequences. Using the yeast system, MSH2 and PMS1 are altered and the affects on the resulting yeast are analyzed. The system used allowed for recombination that would result in a predictable outcome depending on the specific gene conversion that occurred. Selva *et al.* the use of non-homologous sequences (Figure 1) and report the affect of various alterations in recombination of the various strains (Tables 2 and 3).

Thus for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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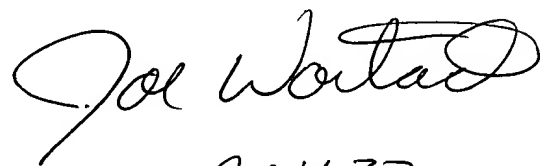
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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